



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/030,944 | 09/03/2003 | Alfred Jonczyk | MERCK 2360 | 6331 |

23599 7590 08/09/2006

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

| EXAMINER |
|----------|
|----------|

GUDIBANDE, SATYANARAYAN R

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1654

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|----------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/030,944 | | JONCZYK ET AL. | |
| | Examiner | | Art Unit | |
| | Satyanarayana R. Gudibande | | 1654 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 7-23 is/are pending in the application.
- 4a) Of the above claim(s) 8,9 and 21-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7 and 10-20 is/are rejected.
- 7) ☐ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/19/03</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1654

DETAILED ACTION

Applicant's amendments to claims filed on 6/15/06 and the addition of new claims 10-23 is acknowledged.

Any objections and or rejections not specifically addressed are herein considered withdrawn.

Claims 1-3, 7-23 are pending in the application.

Claims 4-6 have been cancelled.

Claims 8 and 9 remains withdrawn from consideration as being drawn to non-elected species.

Claims 21-23 have been withdrawn from further consideration as shown below on the basis of election by original presentation.

Allowable Subject Matter

Applicants elected species and the peptide species of claim 3 are free of art and are allowable.

Claim Objections

Claim 3 contains allowable subject matter but objected to because of the following informalities: Claim depends on a rejected claim 1. Appropriate correction is required.

Response to Arguments/Remarks

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 7 and 10-20, drawn to peptide compound of formula I containing Arg-X1-Asp motif present in the sequence.

Group II, claim(s) 8 and 9, are drawn to method for the treatment or prevention of a disorder related to the function of an $\alpha_v\beta_6$ integrin receptor.

Group III, claim(s) 21-23, drawn to a diagnostic agent comprising a peptide of compound formula I.

The inventions listed as groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: A lack of unity was established for this case in our office action of record 8/23/05. Newly submitted claims 21-23 drawn to a diagnostic agent cannot be a special technical feature because the tripeptide motif that is shared by the invention has been known in the art.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-23 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Withdrawn Rejections

Rejections - 35 USC § 102(b)

The rejection under 102(b) has been withdrawn in view of the applicant's amendments to the claim.

Rejections - 35 USC § 112, Second paragraph

The rejection under 112, second paragraph has been withdrawn in view of the applicant's amendments to the claim.

Maintained Rejections

Rejections - 35 USC § 112, First paragraph

Applicants argue that the examiner asserting that the combined length of the residues would exceed 500-2500 pm in length and hence does not provide enablement for 7-12 residues of these amino acids. Applicants' states that the size feature recited in claim 1 is not placed on the entire peptide compound but rather on the α -aminocarboxylic acid residues which make up R¹.

Applicants argue the fact specification adequately describes the preparation of various salts and solvates recited in the claims (specification page 1, lines 24-25 and the text bridging pages 16 and 17). Applicants further argue that formation of salts and solvates is well established and is both a routine and trivial task for one of ordinary skill in the process.

Applicant's arguments filed on 6/15/06 have been fully considered but they are not persuasive. The claim 1 recites one or 'more' α -aminocarboxylic acid residues, the α -

Art Unit: 1654

aminocarboxylic acid residues having a length of 500-2500 pm. In the absence of a clear definition for 'more' combined with the limitation of claim 2 that recites R1 is 1-10 amino acid selected from the group consisting of Ala, Asn, Asp, Arg, Cys, Gln, Glu, Hcy, His, Hse, Ile, Leu, Lys, Met, Pen, Phe, Pro, Ser, Thr, Trp, Tyr and Val clearly puts the length of the peptide 9-19 mer. The length of the individual Gly (the simplest amino acid) as per the specification is 370 pm and hence the combined length of the R1 will exceed the 2500 pm with just 7 glycine residues. Also, it should be noted that all the naturally occurring amino acids are α -aminocarboxylic acids.

With regards solvates, solvates are chemically distinct compounds and there is inadequate support in the specification for the preparation of salts and solvates. As stated in the previous action dated 1/10/06, "since each solid compound responds uniquely to the possible formation of solvates and hence generalizations cannot be made for a series of related compounds". Therefore, the written description is inadequate to show one skilled in the art as to how to prepare the solvates of numerous peptide compounds claimed in the instant application.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1654

Claim 1, 2, 7 and 10-20 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 91/15515 of Pierschbacher, et al.

In the instant application, applicants claim a peptide compound of formula I,
Cyclo-(Arg-X1-Asp-X2-X3-X4-X5-X6-R1) in which

X1 is Ser, Gly or Thr,

X2 is Leu, Ile, Nle, Val or Phe,

X3 is Asp, Glu, Lys or Phe,

X4 is Gly, Ala or Ser,

X5 is Leu, Ile, Nle, Val or Phe,

X6 is Arg, Har or Lys,

R1 is one or more α -aminocarboxylic acid residues, the α -aminocarboxylic acid residues having a length of 500 to 2500 pm wherein the amino acids mentioned are optionally derivatized, the D and the L forms of the optically active amino acid residues are included, or a physiologically acceptable salts salt or solvate thereof.

Pierschbacher, et al., discloses the cyclic peptide sequence,
G(***X6***)PenGH(***R1***)RG(***X1***)DL(***X2***)R(***X3***)C(***X4***)A(***X5***) (claim 17, page 54), the bold notations in italics in bracket has been added to indicate the position to which the sequence of amino acids corresponds to the recited sequence in the instant application, for example, PenGH represents R1 of the instant application, G represents the X1 of the instant application, etc. Since the claim 1 of the instant application recites that the 'amino acids mentioned are optionally derivatized', derivatization of the simple α -amino acid Glycine produces all other α -amino acids. Therefore, X1 in the disclosed sequence in Pierschbacher, et al., can be Ser, Gly or Thr. Likewise, X3 which

Art Unit: 1654

is Arg in the Pierschbacher, et al., can be Asp, Glu, Lys or Phe; X4 which is Cys in the Pierschbacher, et al., can be Gly, Ala or Ser; X5 which is Ala in the Pierschbacher, et al., can be Leu, Ile, Nle, Val or Phe; X6 which is Gly in the Pierschbacher, et al., can be Arg, Har or Lys.

The sequence disclosed by Pierschbacher, et al., is a 11-mer. As disclosed in the specification of the instant application, each Gly has a length of 370 pm (table on page 5 of the instant application). Therefore, the R1 which is a three amino acid length of the Pierschbacher, et al., corresponds to a length of 1110 pm and hence meets the limitation of the claims 1, 10 and 11.

Again, since the claim 1 recites the limitation that the 'amino acids mentioned are optionally derivatized', the amino acids of claims 2 and 10-20 are considered as optional derivatives of α -amino acid Glycine and hence the sequence disclosed by Pierschbacher, et al., reads on the limitations of claims 2 and 10-20.

Pierschbacher, et al., teaches the composition of peptides as active ingredients in physiologically acceptable carrier (claim 18 of Pierschbacher, et al.), therefore meets the limitation of claim 7.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

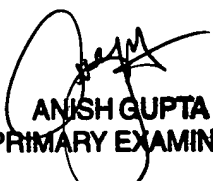
Art Unit: 1654

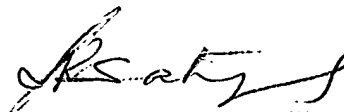
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


ANISH GUPTA
PRIMARY EXAMINER


Satyanarayana R. Gudibande, Ph.D.
Art Unit 1654